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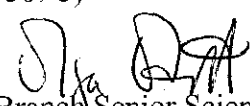
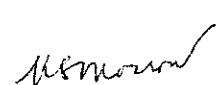
OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 07-MAR-2000

SUBJECT: **Occupational and Residential Exposure and Risk
Assessment/Characterization for Myclobutanil. PC Code: 128857. DP
Barcode: D252850. 264191**

FROM: Dana Vogel, Chemist 
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The Health Effects Division (HED) of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. On order to determine the risk to human health from myclobutanil, HED must determine the potential residential and occupational exposure. This document provides the occupational exposure assessment for myclobutanil formulated as Nova® 40W and Rally® 40W in/on asparagus, snap beans, caneberries, cucurbits, currants, gooseberries, pome fruit, mint, strawberries, and tomatoes. It also provides a residential exposure assessment of the homeowner uses of myclobutanil. The exposure estimates are based on toxicological endpoints identified in the HIARC document dated 9/2/18/99 (HED Doc. No. 013740).

Summary of Use Patterns and Formulations

Myclobutanil is an active ingredient developed by Rohm and Haas for use as a fungicide. For this petition, Rally® and Nova® will be applied to caneberries, gooseberries, currants, pome fruits, cucurbits, asparagus, snap beans, tomatoes, strawberries and mint crops by ground and aerial applications at a maximum of 0.25 pounds ai/Acre (crop dependent). Rally® and Nova® is formulated as a wettable powder packaged in water soluble pouches. Table 1.0 summarizes the use pattern and formulation of myclobutanil.

Table 1.0 Use patterns and formulations of Myclobutanil

Formulation Type, % ai	Use Sites	Equipment for mixing/loading and application	Application Rate	Timing/frequency of application
Wettable Powder in Water Soluble Pouches 40% ai	asparagus	groundboom, aerial	0.125	6-4 apps, PHI=180 days (CA, PHI=30 days)
	beans	airblast, aerial	0.125	4 apps, PHI=0 days
	caneberries	airblast/gb, aerial	0.0625	4 apps, PHI=0 days
	cucurbits	groundboom, aerial	0.0625	10 apps, PHI=0 days
	gooseberries/ currant	airblast/gb, aerial	0.125	8 apps, PHI=0 days
	mint	groundboom, aerial	0.125	3 apps, PH=30 days
	pome fruit	airblast, aerial	0.25	PHI=14 days
	tomatoes	groundboom, aerial	0.10	PHI=0 days
	strawberries	groundboom, aerial	0.75	PHI=0 days

Occupational Exposure and Risk Assessment/Characterization

Based on use patterns, only short- and intermediate-term dermal exposures are expected for both private and commercial applicators. Workers are expected to make as many as 10 applications per season. HIARC has determined that a 50% dermal absorption factor should be applied for the intermediate-term risk assessment. However, a dermal absorption factor is not applicable for the short-term dermal exposure assessment since a dermal dose from a 28-day dermal toxicity study was selected for this time period. Myclobutanil was determined to be a "Group E" chemical (evidence of noncarcinogenicity for humans). Therefore, a cancer risk assessment is not required.

Occupational Handler Exposure

Some chemical-specific data are available to determine the potential risks from worker activities associated with the proposed uses of myclobutanil. The registrant submitted an applicator exposure study for airblast application to grapes (MRID # 404893-03). This study was reviewed by HED in April 1988 and considered acceptable (Memo, M. Firestone, 4/22/88). The unit exposure estimates from the submitted study were used for the airblast, groundboom, and aerial scenarios. For all exposure scenarios (with the exception of the aerial applicator), 'open mixing' and 'open cab' were used to represent a high-end scenario. As specified on the label, all exposures were calculated for workers wearing a single layer of clothing and gloves (with the exception of aerial applicator).

Table 1.1 summarizes the exposure and risk estimates to workers from the proposed uses for myclobutanil. The exposure assessment includes estimates for workers treating at the highest rate prescribed on the proposed label and highest number of acres treated per day. For each application type, the table lists what is assessed as the worst case scenario.

Table 1.1 Exposure and Risk Estimates for Worker Performing Mixing, Loading and Application of Myclobutanil^a

Exposure Scenario	Unit Exposure ^b dermal/inhalation		Maximum AR (lbs ai/A)	Acres/ Day ^c	Average Daily Dose (mg/kg/day) dermal/inhalation		Short-term MOEs dermal/inhalation		Intermediate-term MOE
Mixer/Loader									
Aerial- ^d fixed wing	0.0084	0.00086	0.25	350	0.011	0.0011	9,100	9,100	1,500
Applicator									
Groundboom - open cab	0.0256	0.00043	0.125	80	0.0037	0.0001	27,000	100,000	5,100
Mixer/Loader + Applicator									
Airblast- ^d open mixing	0.0596	0.00172	0.25	40	0.0085	0.0002	11,750	40,000	2,200

ADD = Unit exposure (mg/lb ai) x Application Rate (lbs ai/acre) x Acres Treated /Body weight (BW kg).

Short-Term MOE (dermal or inhalation) = NOAEL/ADD; (Short-term NOAEL = 100mg/kg/day(dermal) and 10 mg/kg/day(inhalation))

Intermediate-term MOE = NOAEL/Total ADD (dermal + inhalation); Intermediate-term NOAEL = 10 mg/kg/day (dermal-corrected for 50% dermal absorption) and 10 mg/kg/day (inhalation)

a-Workers wearing long sleeved shirts, long pants, and gloves .

b-Unit exposures from chemical specific study (Memo, M. Firestone, 4/22/88) and adjusted for application rate.

c-Default acreage obtained from Default Daily Area Treated, Exposure Sac, 7/20/98.

d-Adjusted for application rate.

All short- and intermediate-term MOEs are >100. Since HED's level of concern for myclobutanil is for MOEs below 100, all worker exposures are expected to be below the level of concern.

Occupational Post-Application Exposure

Chemical-specific data are available to determine the potential risks from post-application activities associated with the proposed uses of myclobutanil. The registrant submitted a DFR study on grapes for myclobutanil (MRID # 404893-02). This study was reviewed by HED in June 1988 and considered acceptable (Memo, F. Davido, 6/11/88). In the DFR study, three sites were treated with five applications of myclobutanil at 0.125 lbs ai/acre. With an application rate of 0.10 lbs ai/Acre, a maximum of 5 applications per season, a PHI of 0 days, and hand harvesting activities, tomato crops represent the post-application scenario with the greatest potential for exposure. Therefore, the submitted study is acceptable to assess post-application exposures and risks from the proposed uses of myclobutanil.

Based on the submitted data, the highest DFR is calculated as **0.175 ug/cm²** on day 0 (2 hours after final application). Generic transfer coefficients, ranging from 10,000 ug/cm² to 2,500 ug/cm² were used to represent the full range of dermal transfer potential associated with the proposed uses (Transfer Coefficients Surrogate Table, HED Exposure Scientific Assessment Council (ExpoSAC)). A risk assessment was conducted using the assumptions listed in Table 1.2.

Table 1.2 Post-application Exposure to Myclobutanil

Exposure Scenario	Lowest TC ^a cm ² /hr	Highest TC ^a cm ² /hr	DFR ^b ug/cm ² dat = 0	ADD mg/kg/day (low TC)	ADD mg/kg/day (high TC)	MOE low		MOE high	
						short	interm	short	interm
Hand harvest for fruits/vegetables	2,500	10,000	0.175	0.05	0.20	2000	400	500	100

^a TC (Default Transfer Coefficient for Agricultural Activities, ExpoSac, 5/7/98)

^b Chemical specific study submitted by registrant and reviewed by HED (Memo, F.Davido, 6/11/88)

$$ADD = DFR \left(\frac{\text{ug}}{\text{cm}^2} \right) \times TC \left(\frac{\text{cm}^2}{\text{hr}} \right) \times \frac{8 \text{ hours}}{\text{day}} \times \text{Conversion factor} \left(\frac{0.001 \text{ mg}}{\text{ug}} \right) \times \frac{1}{70 \text{ kg BW}}$$

$$MOE_{\text{dermal}} = \frac{NOAEL \text{ (mg / kg / day)}}{ADD}, \text{ for short and intermediate}$$

Short-term NOAEL = 100mg/kg/day(dermal)

Intermediate-term NOAEL = 10 mg/kg/day (dermal-corrected for 50% dermal absorption)

For short-term exposure scenarios, the MOE for the worker with the highest post-application exposure is 500. For intermediate-term post-application exposure, the MOE are estimated to be 100 and greater. These estimates indicate that the risks from post-application exposure from the proposed uses do not exceed the HED's level of concern.

Restricted Entry Interval (REI)

The proposed label lists a **24-hour** REI. Estimates based on chemical specific data indicate that a 24 hour REI is acceptable.

Incident Reports

There are incidents of human exposure for myclobutanil. In July 1993, several workers complained of headaches, diarrhea, nausea and bloody noses 3 days after spraying Rally. In April 1997, 16 workers complained of nausea, vomiting and skin and eye irritation after performing seed treatment with Nuflow M. In September 1995, REFS reports incidents of children eating tainted sunflower seeds and of aerial drift. None of the reported incidents have been confirmed.

Residential Exposure and Risk Assessment/Characterization

End-use products containing the active ingredient, myclobutanil, are marketed for homeowner use on turf, roses, flowers, shrubs and trees. Recommended applications of the soluble concentrate are made with a hose-end or trigger bottle sprayer. The homeowner use with the greatest potential for exposure is small scale lawn application. Since myclobutanil is applied at 7 to 14-day intervals, only short-term exposure is expected for the residential handler. Intermediate-term exposures are expected for residential post-application scenarios. HIARC has determined that a 50% dermal absorption factor should be applied for intermediate-term risk assessments. However, dermal absorption is not required for the short-term dermal exposure assessment since a dermal dose from a 28-day dermal toxicity study was selected for this time period.

Residential Handler Exposures

Based on the residential use-patterns associated with myclobutanil, there is potential for exposures to handlers of myclobutanil. In order to present a high-end scenario of residential exposure, it was assumed that one person would complete all mixing, loading and application of myclobutanil. Exposure scenarios were assessed, at the maximum application rate, for mixing, loading, and application of a soluble concentrate product by trigger bottle sprayer (treating ornamental plants), and by hose-end sprayer (treating turfgrass) to represent the worst-case scenario for the proposed uses. There are no chemical specific data available to support the residential use scenarios of myclobutanil. Therefore, the PHED v 1.1 surrogate table was used to represent the highest potential for exposure from homeowner application of myclobutanil. Short-term dermal and inhalation exposure and risk assessments for homeowners are presented in Table 1.3.

Table 1.3 Baseline Short-Term Exposure and Risk Assessments for Homeowner Use of Myclobutanil

Exposure Scenario-Mix/Load/Apply	Unit Exposures (mg/lb ai) ^a		AR (lb ai/acre) ^b	Acres/Day ^c	Total Daily Dose (mg ai/kg/day) ^d		Short-Term MOE ^e Dermal/Inhalation		Combined MOE- turf + ornamental treatment Dermal/Inhalation ^f	
	Dermal	Inhalation			Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation
Garden Hose application to lawn turfgrass	30	0.01	0.62	0.50	1.3x10 ⁻¹	4.4x10 ⁻⁵	7.7x10 ²	2.4x10 ⁵	7.5x10 ²	2.3x10 ⁵
Trigger Sprayer application to ornamentals	100	0.03	0.01	0.25	3.6E-03	1.1x10 ⁶	2.8x10 ⁴	9.3x10 ⁶		

a PHED Version 1.1 data in the Draft SOPs for Residential Exposure Assessments dated December 18, 1997, represents short pants, short sleeve shirt, no gloves, and open loading. Low confidence (9-80 replicates of ABC grade data) for dermal exposure. Medium confidence (80 replicates of ABC grade data) for inhalation.

b Myclobutanil label, EPA reg # 9688-123

c Draft SOPs for Residential Exposure Assessments dated December 18, 1997.

d Total Daily Exposure (mg ai/day) = Unit exposure (mg/lb ai) x Application Rate (lbs ai/acre) x Acres Treated/body weight (BW kg).

e Short-term MOE = NOAEL (mg/kg/day)/Daily Dose (mg/kg/day); NOEL = 100mg/kg/day for dermal and 10 mg/kg/day for inhalation.

f Combined Dermal MOE = NOAEL/Total Daily Dose (dermal exposure-treating turf + dermal exposure-treating ornamentals).

g Combined Inhalation MOE = NOAEL/Total Daily Dose (inhalation exposure-treating turf + inhalation exposure-treating ornamentals).

All calculated MOEs are greater than 100 and, therefore, below HED's level of concern. Assuming that a homeowner treats his/her lawn and garden plants/trees on the same day, the combined short-term MOEs are **750** and **2.3E+05** for dermal and inhalation, respectively.

Residential Post-Application Exposure

Potential residential exposures are expected following applications to lawns and ornamental garden sites. Chemical-specific data are available to determine the potential risks from post-application activities. The registrant submitted a DFR study on grapes for myclobutanil (MRID # 404893-02). This study was reviewed by HED in June 1988 and considered acceptable (Memo, F. Davido, 6/11/88). Short-term post-application exposure estimates were done using the study determined DFR of 0.175 ug/cm² (on day 0). For intermediate-term post-application exposure, an average of DFRs from day 0 through day

14 was used.

The post-application risk assessment is based on DFR data from the submitted study on grapes and generic assumptions as specified by the recently revised Residential SOPs. Changes to the Residential SOPs have been proposed that alter the residential post-application scenario assumptions. The proposed assumptions are expected to better represent residential exposure and are still considered to be high-end, screening level assumptions. HED management have authorized the use of the revised residential SOPs that were presented to the FIFRA SAP in September 1999. Therefore, HED has used the most recently proposed assumptions to calculate exposure estimates.

Based on the use pattern, exposure to myclobutanil-treated ornamentals is expected to be incidental and short-term. Both short- and intermediate-term exposures are expected following lawn applications of myclobutanil. Short-term aggregate post-application exposure for the adult was done for dermal exposure to treated turf and ornamentals. Since there is no intermediate-term exposure for the residential handler, there is no aggregate intermediate-term exposure for the adult.

Short-term, non-dietary ingestion exposure to toddlers is not assessed since HIARC did not select an acute dietary or oral endpoint applicable to infants and children. Therefore, short-term toddler exposure consists of dermal post-application exposure only. However, intermediate-term, non-dietary ingestion exposure for toddlers is possible and was assessed using the intermediate-term dose and endpoint identified from the two generation reproduction toxicity study in rats. Intermediate-term aggregate exposure for toddlers combines non-dietary ingestion and dermal exposure from treated turf. Residential post-application exposures are summarized in Table 1.4.

Table 1.4 Residential Post-application^a

Scenario	DFR ($\mu\text{g}/\text{cm}^2$) ^b day 0/ day 0-14		Daily Dose ($\text{mg}/\text{kg}/\text{day}$) ^c short/interm		Short-Term MOE ^d	Intermediate- Term MOE ^d	Combined MOE short ^e /interm ^f	
Adult dermal - turf	0.175	0.105	0.073	0.022	1400	910	1000	--
Adult dermal - ornamentals			0.017	--	6000	--		
Toddler- hand-to-mouth			--	0.0013	--	7500	--	510
Toddler dermal - turf			0.12	0.036	830	550		
Youth dermal - ornamentals			0.0074	--	14000	--	--	--

a The level of concern is for MOEs below 100.

b DFR based on a registrant submitted study reviewed by HED (Memo, F.Davido, 6/1/88).

c **Short-term Turf** Daily Dermal Dose = DFR ($\mu\text{g}/\text{cm}^2$) x Tc (14,500 cm^2/hr for adults and 5,200 cm^2/hr for toddlers) x (1 $\text{mg}/1,000 \mu\text{g}$ unit conversion) x 2 hours/day/ Body Weight (BW kg).

Short-term Ornamentals Daily Dermal Dose = DFR ($\mu\text{g}/\text{cm}^2$) x Tc (10,000 cm^2/hr for adults and 5,000 cm^2/hr for youths) x (1 $\text{mg}/1,000 \mu\text{g}$ unit conversion) x hours/day (0.67 for adults and 0.33 for youths) / Body Weight (BW kg -70 for adults and 39 for youths).

Intermediate-term Turf Daily Dermal Dose = DFR ($\mu\text{g}/\text{cm}^2$) x Tc (7,300 cm^2/hr for adults and 2,600 cm^2/hr for toddlers) x (1 $\text{mg}/1,000 \mu\text{g}$ unit conversion) x 2 hours/day/ Body Weight (BW kg).

Intermediate Turf Hand to mouth = DFR X 20 cm^2/event X 9.5 events/hr X 2hrs/day X 50% mouthing removal rate X conversion factor (1 $\text{mg}/1000\mu\text{g}$) /BW (15 kg).

d MOE = NOEL /Daily Dose; Short-term NOAEL = 100 $\text{mg}/\text{kg}/\text{day}$ (for dermal); Intermediate-term NOAEL = 10 $\text{mg}/\text{kg}/\text{day}$ (for dermal(incorporating a 50% dermal absorption factor) and oral-hand2mouth exposures).

e Aggregate Short-term MOE (for adult)= NOAEL/Total Daily Dose (dermal to turf+ dermal to ornamentals); NOAEL = 100 $\text{mg}/\text{kg}/\text{day}$.

f Aggregate Intermediate MOE (for toddler)= NOAEL/Total Daily Dose (dermal + hand2mouth); NOAEL = 10 $\text{mg}/\text{kg}/\text{day}$.

HED's level of concern for myclobutanil is for MOEs below 100. The aggregate short-term post-application MOE is estimated to be 1000 for adults. The aggregate intermediate-term post-application MOE is estimated to be 510. These estimates indicate that potential post-application exposures to myclobutanil are below HED's level of concern.

The total dermal exposure for the handler treating both turf and ornamentals in one day can be aggregated to the total dermal post application exposure to turf and ornamentals for the short-term duration. Since intermediate exposure is not expected for the handler or for post-application to ornamentals, an aggregate intermediate-term assessment for handler and post-application exposures is not warranted. Table 1.5 lists the combined residential exposures for adults.

Table 1.5 Combined Residential Handler and Post-application Dermal Exposures

Scenario	Short-term MOE	Combined Short-term MOE
Handler applying to turf and ornamentals	750	430
Adult post-application exposure to turf and ornamentals	1000	

Combined Short-term dermal MOE = NOAEL/Total Daily Dose (handler exposure + post-application exposure); NOAEL = 100 $\text{mg}/\text{kg}/\text{day}$.

The aggregate short-term MOE is calculated to be 430 and is therefore below HED's level of concern.

cc (no attachments): Chemical file, D. Vogel (RAB1), O.Odiott (RAB1)

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